PET FOOD INSTITUTE
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March 24, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No.02N-0278

Dear Sir or Madam:

On behalf of its members, the Pet Food Institute (PFI) presents the following comments in response to the Food and Drug Administration's Notice of Proposed Rulemaking entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Bioterrorism Act) (68 Federal Register 5428, February 3, 2003). PFI represents companies that manufacture 97 percent of the dog and cat food sold in the United States and supports the overall intent of the Bioterrorism Act to improve food and feed safety. However, the proposed rule, as currently drafted, would pose a number of burdens on the US pet food industry and its suppliers that would not contribute to the overall goal of improved food safety.

PFI joins with a number of other food and feed-related trade associations who view the proposed rule as going beyond the statutory authority granted by the Bioterrorism Act. Though the goals of the rule are laudable, their effect on the food and feed industry will be damaging. For example, and as PFI will comment in more detail below, the proposed rule will impose a huge recordkeeping and logistical burden on the pet food industry.

Commercial pet food production in the US relies extensively on a number of imported ingredients, including animal protein-derived

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ingredients such as lamb meal, as well as certain vitamin supplements, preservatives and packaging materials. All of these would be subject to the prior notice rule regardless of their source. PFI will comment on certain provisions of the rule below and seeks clarification on a number of points to facilitate compliance once the rule is finalized and implemented.

Amendments & Updates

In its proposed rule, the agency seeks comment on who should be permitted to provide prior notice of an imported article. This question as to who is allowed to give the notice is integral to the discussions on amendments and updates. Under the proposed rule, only the US importer or agent, is allowed to make a prior notice declaration (§1.285).[1] This portion of the rule is not flexible enough to cover unexpected events or supply changes that are inherent in international trade. For example, the proposed rule says the submitter of the prior notice is responsible for the accuracy and timeliness of the notice. The submitter, who is required to be the US importer, may not have complete information or up-to-date arrival locations or times. Therefore it is imperative that carriers be allowed to provide prior notices for all deliveries that may have been substantially affected by weather or other events outside of the control of the importer.

This is contrary to the assumption contained in the proposed rule, "FDA believes that in most circumstances information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States" (p. 5433). Since severe weather, mechanical failures or other unforeseeable events can dramatically alter departure and arrival times and locations, carriers should be allowed to amend and update prior notices with the FDA on the behalf of the US importer. In addition, §1.285(b) clearly recognizes the need for carriers to be allowed to submit prior

[1] PFI would also urge the agency to broaden the definition of "agent" in the final regulations to include US-based employees of foreign companies that export articles to the United States.

notices when articles are imported for in-bond movement through the US. The circumstances affecting the notice, amendments and updates for both types of importation are the same and thus show the need to permit carriers to issue notice in all instances.

As an alternative to allowing carriers to file original prior notices on behalf of US importers, at a bare minimum, carriers should be permitted to amend and update notices. FDA clearly recognized this need in the proposed rule when it stated "one person may not possess all of the information and that some practices regarding the flow of information about food imports will have to change to ensure that the submitter has all of the information needed to submit a prior notice . . ." (p. 5433) By allowing a carrier to amend or update a notice, the agency can still achieve its statutory requirements while not causing undue disruption in trade or forcing expensive alterations in business practices.

Beyond the necessity of allowing carriers to amend and update notices, the requirements for their use also needs further consideration prior to the implementation of this rule. Specifically, under the proposed rule the agency will only permit submitters to amend prior notices for product identity information that cannot be completed when the initial notice is filed. The rule would specifically prohibit amendments when a shipper "tops off a container." (p. 5434) Since the agency has already been informed about the shipment, regardless of what is added at the last minute, and has already received information regarding the shipment's origin, manufacturer, grower, etc., the agency already has enough information to make a determination as to whether or not articles in the shipment could pose a threat.

For example, additional material added at the last minute to a shipment, when declared to the agency through the amendment process, would not contribute significantly to agency inspection decisions if the articles were from the same manufacturer, grower, etc. Since amendments to quantity are already permitted

(§1.291) PFI would request the agency reconsider this prohibition and adopt in the final rule circumstances under which shippers could amend notices thus allowing the full utilization of transport space even when that space is filled with additional items not explicitly declared in the original prior notice. A prohibition on this practice would make some shipments, particularly of smaller items, less cost competitive and may reduce the overall availability of some products.

Prior Notice Time Requirement

Under the proposed rule the importer of an article must provide FDA notice of that importation at least by 12:00pm the day before arrival and no longer than five days prior to the article's arrival.[2] PFI would urge the agency to reconsider this requirement and apply the prior notice time limitations to the mode of transport. For example, articles imported by ship are much easier to track and determine an accurate time of arrival, in that events delaying an arrival time may be more evident (e.g. weather delays or mechanical failures). However, imports arriving by air, such as small consignments of materials such as vitamin supplements, may not be required by an importer until well within the required notification time.

Manufacturers who rely on "just-in-time" supplies will not be able to comply with these arbitrary time notification periods and will be forced to drastically alter their production methods. A transportation-based notice system (e.g. "wheels up" for aircraft, with the statutory minimum of eight hours) would allow the FDA a reasonable amount of time to move required personnel to inspect shipments while causing the least amount of disruption to businesses dependent on the importation of materials.

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[2] The Bioterrorism Act states that an eight-hour minimum is required should the FDA not issue regulations. No reason is given for the minimum requirement of noon the day before an article arrives.

Countries of Origin

The proposed rule requires the prior notice of an imported article include the country of origin (§1.277). In the rule, the agency is requesting comment on whether this information should include "intermediate destinations." In many instances, an imported article may pass through a number of ports or stops in a variety of countries and never be unloaded. In addition, a US importer in most cases has no control of which ports or stops a carrier may make. It would be unreasonable and burdensome, while not improving the safety and security of the food supply, to require importers to learn and report this information as a part of the prior notice requirements.

Bulk Commodities from Various Growers

Under proposed §1.288(g), prior notice filers are required to list contact information for "all growers, and the growing location if different from business address, if known at time of submission." PFI would request clarification as to when an importer must be aware of the grower(s) of imported articles that are shipped in bulk and are from various growers and growing location. In addition, since it is not possible to segment bulk commodity shipments into distinct articles, would individual prior notices be required for each and every portion of the same commodity that may be contained in a bulk shipment?

Conclusion

PFI appreciates the opportunity to offer comments to this proposed rule implementing the prior notice provisions of the Bioterrorism Act. PFI will continue to work with the Agency and other federal and state government divisions to further increase the safety of the country's food supply. The Bioterrorism Act contains a number of provisions that can, if carefully implemented, accomplish improvements in food security. PFI, along with many other food and animal feed-related trade associations, commends the Agency's efforts in developing the proposed rule ahead of

the statutory deadline. The proposed rule, however, needs to be completely considered in light of all the comments received by the Agency to determine if it meets its statutory requirement and does not duplicate the security efforts of other federal agencies. The goal of the final rules issued by the FDA should be an improvement in the safety and security of the nation's food and feed supply while not imposing over-reaching and unnecessary burdens.

Sincerely,

Duane H. Ekedahl
Executive Director